

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: AVAULTA PELVIC SUPPORT SYSTEMS PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

REBECCA SMITH,)
Plaintiff,)
v.) CIVIL ACTION FILE
C. R. BARD, INC.,)
MITCHELL E. NUTT, M.D.,)
COVIDIEN INC.,)
COVIDIEN PLC,)
COVIDIEN INTERNATIONAL)
FINANCE, SA,)
COVIDIEN TREVOUX, SCS,)
MAREANE, SA,)
FLOREANE MEDICAL IMPLANTS SA,)
and SOFRADIM PRODUCTION SAS,)
Defendants.)

SECOND AMENDED COMPLAINT

COMES NOW Rebecca Smith as Plaintiff herein and hereby files this Second Amended Complaint, showing the Court as follows:

PARTIES, JURISDICTION AND VENUE

1.

Plaintiff is a citizen of the State of West Virginia.

2.

Defendant C. R. Bard, Inc. ("Bard") is a New Jersey corporation with its principal place of business in New Jersey. All acts and omissions of Bard as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

3.

Defendant Mitchell E. Nutt, M.D. ("Dr. Nutt") is a citizen of the State of Ohio.

4.

Defendant Covidien Inc. ("Covidien Inc.") is a Delaware Corporation with its principal place of business in Massachusetts. All acts and omissions of Covidien Inc. as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

5.

Defendant Covidien plc ("Covidien plc") is an Irish public limited company with its principal place of business in Massachusetts. All acts and omissions of Covidien plc as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

6.

Defendant Covidien International Finance, SA ("CIFSA") is a Luxembourg company with its principal place of business in Luxembourg. All acts and omissions of CIFSA as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

7.

Defendant Covidien Trevoux, SCS ("Covidien Trevoux") is a French company with its principal place of business at 116 Avenue Du Formans, Trevoux, France 01600. All acts and omissions of Covidien Trevoux as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

8.

Defendant Mareane, SA ("Mareane") is a French company with its principal place of business at 116 Avenue Du Formans, Trevoux, France 01600. All acts and omissions of Mareane as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

9.

Defendant Floreane Medical Implants SA ("Floreane") is a

French company with its principal place of business at 116 Avenue Du Formans, Trevoux, France 01600. All acts and omissions of Floreane as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

10.

Defendant Sofradim Production SAS ("Sofradim") is a French company with its principal place of business at 116 Avenue Du Formans, Trevoux, France 01600. All acts and omissions of Sofradim as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

11.

Plaintiff is seeking damages in excess of \$75,000.00. Subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1332.

12.

Defendants have significant contacts with the Southern District of West Virginia such that they are subject to personal jurisdiction within said district.

13.

A substantial part of the events and omissions giving rise

to Plaintiff's causes of action occurred in the Southern District of West Virginia.

14.

Pursuant to 28 U.S.C. § 1391(a), venue is proper in the Southern District of West Virginia.

FACTUAL BACKGROUND

15.

Plaintiff was implanted with the Avaulta Anterior and Posterior BioSynthetic Support Systems (the "Products") during surgery performed by Dr. Nutt at St. Mary's Medical Center in Huntington, West Virginia.

16.

The Products were implanted in Plaintiff to treat her pelvic organ prolapse, the use for which the Products were designed, marketed and sold.

17.

As a result of having the Products implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, and permanent and substantial physical deformity, has undergone and will undergo corrective surgery or surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages, and other damages.

18.

Floreane, Sofradim and Covidien Inc. designed and manufactured the Avaulta BioSynthetic Support Systems, including the Products that were implanted in Plaintiff.

19.

Floreane, Sofradim and Covidien Inc. have admitted *in judicio* that they are the designers and manufacturers of the Avaulta Biosynthetic Support Systems, including the Products that were implanted in Plaintiff.

20.

Bard marketed, packaged, labeled, sold and distributed the Avaulta Anterior and Posterior BioSynthetic Support Systems in the United States, including the Products that were implanted in Plaintiff.

21.

Sofradim is, and at all times relevant was, a subsidiary of Floreane. Floreane is the sole shareholder of Sofradim. Floreane owns 100% of the capital of Sofradim. Floreane controls 100% of the voting rights of Sofradim. Floreane appoints the officers and directors of Sofradim. Floreane has the power to remove the officers and directors of Sofradim.

22.

Floreane and Sofradim share the same principal place of business, 116 Avenue Du Formans, Trevoux, France 01600.

23.

Sofradim is a "production line" of Floreane.

24.

Floreane and Sofradim are members of a tax consolidation group, or "intégration fiscale," organized under French law, whereunder their corporate income taxes are calculated on the basis of their aggregated profits and losses, rather than individually. Floreane is the "head" of this tax group, and files a consolidated tax return for the group and pays taxes on behalf of the group.

25.

Floreane is liable for any acts and/or omissions by or through Sofradim. Sofradim is so organized and controlled and its business conducted in such manner as to make it merely an alter ego or business conduit of Floreane. Because Sofradim's assets and capital are subject to the ownership and control of Floreane, Sofradim is undercapitalized and the failure to disregard Sofradim's corporate form would result in the inequitable and unjust result that Plaintiff may be unable to satisfy any judgment ultimately obtained against Sofradim. Sofradim acts as agent for Floreane. Floreane and Sofradim combine their property and labor in a joint undertaking for profit, with rights of mutual control.

26.

Covidien Trevoux and Mareane are direct shareholders of Floreane.

27.

Covidien Inc., Covidien Trevoux, Mareane, Floreane and Sofradim are subsidiaries of Covidien plc and are wholly-owned by CIFSA.

28.

Covidien plc is a holding company, the purpose of which is to co-ordinate the administration, finances and activities of its subsidiary companies, including Covidien Inc., Sofradim and Floreane, and to act as managers and to direct or coordinate the management of its subsidiary companies or of the business, property and estates of any subsidiary company, including Covidien Inc., Sofradim and Floreane.

29.

The Articles of Association of Covidien plc provide in part that it shall indemnify any person who is serving or has served at the request of the Company as a director or executive officer of another company, joint venture, trust or other enterprise, including any Company subsidiary against any expenses, including attorney's fees, judgments, fines, and amounts paid in settlement actually and reasonably incurred by him or her in connection with any threatened, pending, or completed action,

suit or proceeding, whether civil, criminal, administrative or investigative, to which he or she was, is, or is, threatened to be made a party, or is otherwise involved.

30.

CIFSA is a holding company established by Covidien plc to own the operating subsidiaries of Covidien plc, to issue notes, and to perform treasury operations for Covidien plc.

31.

When Covidien plc's immediate predecessor, Covidien Ltd., purchased Floreane, Covidien Ltd. acquired Floreane's assets and also assumed Floreane's liabilities. Covidien plc assumed Floreane's liabilities when it merged with and into Covidien Ltd.

32.

The financial accounts of Covidien Trevoux, Mareane, Floreane and Sofradim are consolidated within those of CIFSA.

33.

Covidien Trevoux, Mareane, Floreane, Sofradim, are part of "Le Comite d'entreprise de l'Unite Economique et Sociale," ("UES") an economic and social unit organized under French law, which is defined as the "co-existence of an economic and social unity."

34.

Covidien Trevoux, Mareane, Floreane, and Sofradim all share the same principal place of business, 116 Avenue Du Formans, Trevoux, France 01600.

35.

Covidien Trevoux, Mareane, Floreane and Sofradim are parties to a cash pooling agreement, or "convention de trésorerie," the proceeds of which are ultimately distributed to Covidien plc and/or CIFSA.

36.

Covidien plc, CIFSA, Covidien Trevoux, Mareane, Floreane and Sofradim share common officers and directors. Michel Therin is President of both Mareane and Floreane, "Directeur Général Délégué" for Sofradim, as well as "Vice President of Soft Tissue Repair and Biosurgery for Covidien plc. CIFSA's Managing Director (Principal Executive, Financial and Accounting Officer), Michelangelo Stefani, is the non-partner manager for Covidien Trevoux and a member of the Board of Directors of Floreane.

37.

CIFSA conducts no independent business of its own, and its income is derived entirely from the continuing operations and cash flow through distributions from its subsidiaries, including Floreane and Sofradim.

38.

CIFSA and/or Covidien plc own any and all trademarks and registered marks associated with Covidien Trevoux, Mareane, Floreane and Sofradim.

39.

Covidien plc, CIFSA, Covidien Trevoux and Mareane are liable for any acts and/or omissions by or through Sofradim or Floreane. Floreane and Sofradim are so organized and controlled and their business conducted in such manner as to make them merely alter egos or business conduits of Covidien plc, CIFSA, Covidien Trevoux and Mareane. Because Sofradim's and Floreane's assets and capital are subject to the ownership and control of Covidien plc, CIFSA, Covidien Trevoux and Mareane, Sofradim and Floreane are undercapitalized and the failure to disregard Sofradim's and Floreane's corporate form would result in the inequitable and unjust result that Plaintiff may be unable to satisfy any judgment ultimately obtained against Sofradim and/or Floreane. Floreane and Sofradim act as agents for Covidien plc, CIFSA, Covidien Trevoux and Mareane. Floreane and Sofradim combine their property and labor with that of Covidien plc, CIFSA, Covidien Trevoux and Mareane in a joint undertaking for profit, with rights of mutual control.

40.

As a result of Dr. Nutt's care and treatment of her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, permanent and substantial physical deformity, and loss of a bodily organ system, has undergone and will likely undergo future corrective surgery or surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages, and other damages.

41.

Plaintiff has fully complied with the pre-suit notification requirements of West Virginia Code § 55-7B-6.

CAUSES OF ACTION AGAINST BARD, COVIDIEN INC., FLOREANE AND SOFRADIM

COUNT I: NEGLIGENCE

42.

Plaintiff incorporates by reference paragraphs 1-41 of this Complaint as if fully set forth herein.

43.

Defendants Bard, Covidien Inc., Floreane and Sofradim (hereinafter, "Defendants") had a duty to individuals, including Plaintiff, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Products.

44.

Defendants were negligent in failing to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Products.

45.

As a direct and proximate result of Defendants' negligence, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages, and other damages.

COUNT II: STRICT LIABILITY - DESIGN DEFECT

46.

Plaintiff incorporates by reference paragraphs 1-41 of this Complaint as if fully set forth herein.

47.

The Products implanted in Plaintiff were not reasonably safe for their intended uses and were defective as a matter of law with respect to their design.

48.

As a direct and proximate result of the Products' aforementioned defects, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic

loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages, and other damages.

49.

Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

COUNT III: STRICT LIABILITY - MANUFACTURING DEFECT

50.

Plaintiff incorporates by reference paragraphs 1-41 of this Complaint as if fully set forth herein.

51.

The Products implanted in Plaintiff were not reasonably safe for their intended uses and were defective as a matter of law with respect to their manufacture.

52.

As a direct and proximate result of the Products' aforementioned defects, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages, and other damages.

53.

Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

COUNT IV: STRICT LIABILITY - FAILURE TO WARN

54.

Plaintiff incorporates by reference paragraphs 1-41 of this Complaint as if fully set forth herein.

55.

The Products implanted in Plaintiff were not reasonably safe for their intended uses and were defective as a matter of law due to their lack of appropriate and necessary warnings.

56.

As a direct and proximate result of the Products' aforementioned defects, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages, and other damages.

57.

Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

COUNT V: BREACH OF EXPRESS WARRANTY

58.

Plaintiff incorporates by reference paragraphs 1-41 of this Complaint as if fully set forth herein.

59.

Defendants made assurances to the general public, hospitals and health care professionals that the Products were safe and reasonably fit for their intended purpose.

60.

Plaintiff and/or her health care provider chose the Products based upon Defendants' warranties and representations regarding the safety and fitness of the Products.

61.

Plaintiff, individually and/or by and through her physician, reasonably relied upon Defendants' express warranties and guarantees that the Products were safe, merchantable, and reasonably fit for their intended purpose.

62.

Defendants breached these express warranties because the Products implanted in Plaintiff were unreasonably dangerous and defective and not as Defendants had represented.

63.

Defendants' breaches of their express warranties resulted in the implantation of unreasonably dangerous and defective

products in Plaintiff's body, placing Plaintiff's health and safety in jeopardy.

64.

As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages, and other damages.

COUNT VI: BREACH OF IMPLIED WARRANTY

65.

Plaintiff incorporates by reference paragraphs 1-41 of this Complaint as if fully set forth herein.

66.

Defendants impliedly warranted that the Products were merchantable and were fit for the ordinary purpose for which they were intended.

67.

When the Products were implanted in Plaintiff to treat her pelvic organ prolapse, the Products were being used for the ordinary purpose for which they were intended.

68.

Plaintiff, individually and/or by and through her physician, relied upon Defendants' implied warranty of merchantability in consenting to have the Products implanted in her.

69.

Defendants breached this implied warranty of merchantability because the Products implanted in Plaintiff were neither merchantable nor suited for their intended use as warranted.

70.

Defendants' breaches of their implied warranties resulted in the implantation of unreasonably dangerous and defective products in Plaintiff's body, placing Plaintiff's health and safety in jeopardy.

71.

As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages, and other damages.

COUNT VII: PUNITIVE DAMAGES

72.

Plaintiff incorporates by reference paragraphs 1-71 of this Complaint as if fully set forth herein.

73.

Defendants' conduct in designing, manufacturing, marketing, labeling, packaging and selling the unreasonably safe and defective Products amounted to willful, wanton, and/or reckless conduct and/or criminal indifference to civil obligations affecting the rights of others.

74.

Plaintiff is therefore entitled to an award of punitive damages.

CAUSES OF ACTION AGAINST DR. NUTT

COUNT VIII: NEGLIGENCE

75.

Plaintiff incorporates by reference paragraphs 1-41 of this Complaint as if fully set forth herein.

76.

Dr. Nutt's care and treatment of Plaintiff deviated from the standard of care of the medical profession generally under like or similar circumstances, and was negligent.

77.

As a direct and proximate result of Dr. Nutt's aforementioned negligence, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages, and other damages.

WHEREFORE, Plaintiff demands trial by jury, judgment against Defendants C. R. Bard, Inc., Mitchell E. Nutt, M.D., Covidien Inc., Covidien plc, Covidien International Finance, SA, Covidien Trevoux, SCS, Mareane, SA, Floreane Medical Implants SA, and Sofradim Production SAS, jointly and severally, for compensatory and punitive damages in an amount exceeding \$75,000, as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which she is entitled.

PLAINTIFF DEMANDS A TRIAL BY JURY.

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